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510(k) Safety Summary

A. Name of Device

- Trade Name: Stellartech Coagulation System
- Common Name: Electrosurgical Unit and Accessories
- Classification Name: Device, Electrosurgical Cutting and Coagulation and Accessories (21 CFR 878.4400)

B. Predicate Devices

Device	Premarket Notification
Stellartech Coagulation System	K013139, 12/18/01
Stellartech Coagulation System	K023765, 11/29/02
Stellartech Coagulation System	K032062, 07/29/03

C. Device Description:

The Stellartech Coagulation System consists of the following components.

- Stellartech Coagulation Generator
- Stellartech Coagulation Probe Connection Module
- Stellartech Coagulation Probe
- Optional Stellartech Sizing Probe
- Optional Stellartech Footswitch.

The proximal end of the Stellartech Coagulation Probe connects to the Stellartech Coagulation Probe Connection Module. The proximal end of the Stellartech Coagulation Probe Connection Module cable connects to the Stellartech Coagulation Generator.

D. Indicated Use

The Stellartech Coagulation System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

E. Technical characteristics

The technological characteristics of the Stellartech Coagulation System are substantially equivalent to those of the above listed predicate devices.

F. Summary

By virtue of design, principles of operation, materials and intended use, the Stellartech Coagulation System is substantially equivalent to devices currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2003

Mr. James R. Santos
Senior Quality Engineer
Stellartech Research Corporation
1346 Bordeaux Drive
Sunnyvale, California 94089

Re: K032452
Trade/Device Name: Stellartech Coagulation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 9, 2003
Received: August 11, 2003

Dear Mr. Santos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K032452

DEVICE NAME: Stellartech Coagulation System

INDICATIONS FOR USE:

The Stellartech Coagulation System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

Mark N Milliern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K032452

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use _____

(Per 21 CFR 801.109)